

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
_____)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	
v.)	CIVIL ACTION NO. 99-20593
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

January 26, 2007

The Estate of William Woodward (the "Estate" or "claimant") is a representative claimant seeking benefits from the AHP Settlement Trust ("Trust"), which was established under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth.¹ Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did
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To seek Matrix benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented. To obtain Matrix Benefits, a claimant must establish that there is a reasonable medical basis for his or her claim under the criteria set forth in the Settlement Agreement. Accordingly, a claimant may recover benefits if the attesting physician's reading of the echocardiogram, and thus his or her accompanying Green Form answers, have a reasonable medical basis.

William Woodward, the decedent, died on March 17, 1999. In May 2000, claimant submitted a completed Green Form to the Trust signed by the attesting physician Paul D. Anderson, M.D. Dr. Anderson also submitted a set of verified supplemental answers. Based on echocardiograms dated January 6, 1997,

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not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

July 10, 1998, and October 26, 1998, Dr. Anderson attested in Part II of the Green Form and his supplemental answers that the decedent suffered from moderate mitral regurgitation, moderate aortic regurgitation, a reduced ejection fraction between 50% and 60%, surgery to repair or replace the aortic and/or mitral valve after the use of Pondimin and/or Redux, and death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Moderate or greater aortic regurgitation is defined as a Jet Height/Left Ventricular Outflow Tract Height ratio ("JH/LVOTH") greater than 25% and an ejection fraction is considered reduced if it is measured as less than or equal to 60%. See id. §§ I.22 and IV.B.2.c.(2)(b).

Dr. Anderson also attested to the presence of aortic sclerosis, aortic stenosis, and mitral annular calcification ("MAC"), all of which are reduction factors that would require the payment of benefits on Matrix B-1.³ See Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d). Based on such findings, claimant would be entitled to Matrix B-1, Level V benefits in the amount of \$197,036.

3. Despite the presence of several reduction factors, claimant asserts that it is entitled to payment on the "A" Matrix.

Under the Settlement Agreement, a claimant is entitled to Level V Matrix benefits if his or her death resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery that occurred after ingesting Pondimin and/or Redux. The cause of death must be supported by a statement from the attending Board Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and by the decedent's medical records. See Settlement Agreement § IV.B.2.c.(5)(c).

In the report of the decedent's January 6, 1997 echocardiogram, Peter Wolk, M.D., found the following: (1) a calcified aortic root and aortic valve; (2) annular thickening of the mitral valve; and (3) "moderate aortic insufficiency." Dr. Wolk further concluded that "[n]o significant mitral regurgitation was appreciated" and the "Overall Conclusions" were "[a]bnormal echocardiogram showing severe aortic stenosis with well preserved left ventricular function"

The decedent's July 10, 1998 echocardiogram was performed by Dr. Wolk after claimant underwent aortic valve replacement surgery on January 24, 1997.⁴ Dr. Wolk noted that the prosthetic valve is "seated well" and "appears to be functioning well." Dr. Wolk also found that "[t]rivial aortic insufficiency" and "mild to moderate prosthetic valve stenosis" were present. Finally, Dr. Wolk noted the presence of MAC.

4. The report of this echocardiogram incorrectly states that the valve replacement surgery was in 1996.

In the report of claimant's October 26, 1998 echocardiogram, Dr. Wolk noted that the prosthetic valve "appears to be well seated," although the "aortic valve prosthesis was not well visualized. No excessive calcium noted." Dr. Wolk also found mild to moderate prosthetic valve stenosis, mild aortic regurgitation, and MAC.

In August 2002, the Trust forwarded the claim for review by Keith Churchwell, M.D., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Anderson's findings that the decedent suffered death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery after the use of Pondimin and/or Redux. Instead, Dr. Churchwell found that the decedent's death was caused by asystolic arrest. Dr. Churchwell stated that the "[r]ecords document Asystolic Arrest, Arrhythmic death. No portion of the record states a significant valvular abnormality led to the event. Surgical procedure was two years prior to death." Dr. Churchwell's conclusions appear to be based on claimant's January 6, 1997 echocardiogram. Dr. Churchwell also noted that claimant suffered from aortic stenosis and aortic sclerosis.⁵

5. In its show cause submission, the Trust referred to an audit performed on or about July 9, 2002 by a second auditing cardiologist, Robert Schlesinger, M.D. The Trust states that Dr. Schlesinger had concluded that the decedent's medical records "do not clearly demonstrate a true relation between the valve replacement surgery and death." The Trust, however, did not reference Dr. Schlesinger's entire statement, which reads as
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Based on Dr. Churchwell's conclusion, the Trust issued a post-audit determination denying the Estate's claim.⁶ Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; Pretrial Order ("PTO") No. 2457, Audit Policies and Procedures § VI.⁷ The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On November 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3133 (Nov. 19, 2003).

5(...continued)
follows:

[t]he patient had aortic stenosis possibly related to diet drug use. The patient had aortic valve replacement. He subsequently had some degree of prothetic [sic] aortic stenosis. This may have contributed to the patient's sudden death although the records do not clearly demonstrate a true relation between the valve replacement surgery & death.

6. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claimant is entitled to Matrix benefits.

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). By letter dated March 25, 2002, claimant was notified that his claim was selected for audit. Thus, there is no dispute that claimant's audit and instant appeal are governed by the Audit Policies and Procedures approved in PTO No. 2457.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 20, 2004. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. at § VI.O.

In support of the claim, claimant submitted a declaration from Dr. Anderson dated December 24, 2003, an additional copy of the July 10, 1998 echocardiogram report, and, a January 26, 1997 report by Ronald Becker, M.D., the decedent's surgeon, commenting on the January 24, 1997 aortic valve replacement surgery. In his declaration, Dr. Anderson stated that the aortic valve replacement surgery was "less than

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of a Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. See id. at 158.

successful." In support, he commented that the gradient across the aortic valve decreased from 80 mm Hg to better than a 40 mm Hg after the surgery. He also noted that, after the surgery, the decedent was "left with moderate prostatic [sic] valvular stenosis," and that the risk of that condition is "sudden death due to arrhythmias, heart failure, and angina." The only solution would have been to re-operate, and "it was elected not to do that." Dr. Anderson further stated that there was no sign of underlying coronary artery disease at the time of the decedent's valve replacement surgery and that the arrhythmia from which the decedent died was "due to underlying valvular heart disease."⁹

The surgeon's report noted that, at the time of the surgery, the decedent had a normal coronary anatomy. The report also noted severe aortic stenosis and calcification of the valves. The procedure was described as "going smoothly." Specifically, "[t]he valve appeared to seat nicely."

In response to the Estate's Show Cause submissions, the Trust argued that claimant has failed to demonstrate a reasonable medical basis for Dr. Anderson's representation that the decedent's death resulted from a condition caused by valvular heart disease or valvular replacement surgery. In particular, the Trust asserted that the "[s]urgical procedure was performed

9. The decedent's March 17, 1999 Death Certificate listed the following causes of death: (1) Cardiac Arrest; (2) ASCVD; (3) Diabetes; (4) Hyperlipidemia; and (5) Other Significant Causes: osteoarthritis [sic], hypothyroid.

two years prior to death" and that claimant's death certificate does not indicate that a "significant valvular abnormality" was a cause of death. (emphasis in original).

Dr. Burke, the Technical Advisor, reviewed the record and determined that there was a reasonable medical basis for Dr. Anderson to find that the decedent's death had resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery. Specifically, Dr. Burke determined that the decedent had a number of medical conditions prior to his aortic valve replacement, including mild to moderate aortic regurgitation, concentric left ventricular hypertrophy, a stenotic aortic valve, a sclerotic and calcified aortic valve, MAC, and physiologic mitral regurgitation. He further determined that the decedent underwent aortic valve replacement surgery for his aortic stenosis and, a little over two years after the decedent's valve replacement, he suffered an out of hospital cardiac arrest, had prolonged asystole during resuscitation, and expired. The Technical Advisor concluded that "[t]he most likely cause of death for [the decedent] would be complications related to his valvular heart disease." Dr. Burke also concluded that "the valve replacement surgery was sub optimal [sic]" and "the [decedent] had no other reason evident in the chart for sustaining an out of hospital cardiac arrest besides his known valvular heart disease." Therefore, Dr. Burke found that there was a reasonable medical basis for Dr. Anderson to conclude that

the decedent's death resulted from a condition caused by valvular heart disease or valvular replacement surgery.

In its Response to the Technical Advisor Report, the Trust asserted that, if eligible for Matrix Benefits based on the findings of Dr. Burke, claimant only qualified for Matrix B-1 benefits due to the presence of reduction factors; namely, aortic stenosis and aortic sclerosis. Claimant objected to the Trust's Response to the Technical Advisor Report on the grounds that it raised a new issue regarding the payment of benefits on Matrix B-1, which the Trust did not raise previously because it had asserted that the claim was not payable.

After reviewing the Show Cause Record and Technical Advisor's Report, we find that claimant has met its burden in establishing that the decedent's death resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery. Significantly, the Trust did not dispute or respond to the specific determinations of the Technical Advisor that there was a reasonable medical basis for the findings of Dr. Anderson, claimant's attesting physician. Moreover, the Technical Advisor's conclusions are supported by one of the Trust's auditors, Dr. Schlesinger, who stated that the aortic stenosis was "possibly related" to diet drug use and that the decedent's prosthetic aortic stenosis "may have contributed" to his "sudden death." Although Dr. Schlesinger qualifies this finding by noting the records "do not clearly demonstrate a true relation," this statement is insufficient to raise doubts concerning the

validity of Dr. Anderson's findings or those of the Technical Advisor.

We also conclude that claimant is entitled to benefits on Matrix B-1. Although the Trust initially did not address this issue, the express terms of the Settlement Agreement require payment on Matrix B-1 whenever a reduction factor is present. See Settlement Agreement § IV.B.2.d.(2). It is undisputed that Dr. Anderson attested in Part II of claimant's Green Form that the decedent had aortic sclerosis and aortic stenosis, either of which requires a reduced payment on Matrix B-1. See id. at §§ IV.B.2.d.(2)(c)(i)(c) and (e). Moreover, the decedent's January 1997 and July 1998 echocardiogram reports and the decedent's January 24, 1997 operative report all note the presence of aortic stenosis. While claimant argues that "fairness" should preclude having this issue addressed, it would be unfair if a claimant were to receive benefits to which he or she is not entitled. There is no basis for approving an unwarranted payment of benefits.

For the foregoing reasons, we conclude that claimant has met its burden in proving that there is a reasonable medical basis for its Level V claim. Such payment, however, must be on Matrix B-1. Therefore, we will reverse the post-audit determination by the Trust and order that claimant be paid in accordance with the Settlement Agreement and this Memorandum.

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AND NOW, on this 26th day of January, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is REVERSED and that the Estate of William Woodward is entitled to Matrix B-1, Level V benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement, and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

/s/ Harvey Bartle III
C.J.